Clinical trial results:
A Global, Phase III, Double Blind, Randomized Controlled Study to Compare the Efficacy, Safety & Immunogenicity of LUBT010 with Lucentis® in Patients with Neovascular Age-Related Macular Degeneration.

Summary

EudraCT number	2017-004409-42
Trial protocol	HU BG
Global end of trial date	09 March 2024

Results information

Result version number	v1 (current)
This version publication date	24 March 2025
First version publication date	24 March 2025

Trial information

Trial identification

Sponsor protocol code	LRP/LUBT010/2016/008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Lupin Limited
Sponsor organisation address	Taluka-Mulshi, Pune, India,
Public contact	Clinical Research Unit, Lupin Limited, neelamnkardekar@lupin.com
Scientific contact	Clinical Research Unit, Lupin Limited, neelamnkardekar@lupin.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the equivalence in efficacy of LUBT010 to Lucentis® in terms of visual acuity, in patients with neovascular AMD.

Protection of trial subjects:

Subjects were monitored onsite prior to and following each injection (for at least 60 minutes) to permit any early treatment and appropriate management if needed. If patient experienced red eye, sensitivity to light, pain or developed a change in vision they were instructed to seek immediate care from the study doctor or an ophthalmologist. Other medications that were considered necessary for the subject's welfare and that were not expected to interfere with the evaluation of the study medication could be given at the discretion of the Investigator, with the exceptions: • Any systemic treatment or ocular treatment with an investigational agent • Systemic anti-VEGF therapy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 September 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 162
Country: Number of subjects enrolled	Slovakia: 45
Country: Number of subjects enrolled	Bulgaria: 25
Country: Number of subjects enrolled	Hungary: 9
Country: Number of subjects enrolled	India: 305
Country: Number of subjects enrolled	Russian Federation: 19
Country: Number of subjects enrolled	United States: 35
Worldwide total number of subjects	600
EEA total number of subjects	241

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	89
From 65 to 84 years	464
85 years and over	47

Subject disposition

Recruitment

Recruitment details:

This study was conducted at a total of 78 study centers in 7 countries (Bulgaria, Hungary, India, Poland, the Russian Federation, Slovakia, and the United States of America).

Pre-assignment

Screening details:

Participants who meet the eligibility criteria were randomly assigned to one of the two treatments of this study.

Period 1

Period 1 title	Overall Trial (complete study duration) (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

Double Blind

Arms

Are arms mutually exclusive?	Yes
Arm title	LUBT010

Arm description:

LUBT010 (proposed ranibizumab biosimilar) Intravitreal injection of 0.05 mL (0.5mg).

Arm type	Experimental
Investigational medicinal product name	LUBT010 (proposed ranibizumab biosimilar)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intravitreal use

Dosage and administration details:

0.5 mg administered as intravitreal injection once every month.

Arm title	Lucentis

Arm description:

Lucentis Intravitreal injection of 0.05 mL (0.5mg)

Arm type	Active comparator
Investigational medicinal product name	Lucentis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intravitreal use

Dosage and administration details:

0.5 mg administered as intravitreal injection once every month

Number of subjects in period 1	LUBT010	Lucentis
Started	299	301
Completed	256	269
Not completed	43	32
Adverse event, serious fatal	3	4
Physician decision	2	-
Consent withdrawn by subject	25	17
Adverse event, non-fatal	6	4
Other	3	1
Lost to follow-up	3	2
Protocol deviation	1	4

Baseline characteristics

Reporting groups	
Reporting group title	LUBT010
Reporting group description:	
LUBT010 (proposed ranibizumab biosimilar) Intravitreal injection of 0.05 mL (0.5mg).	
Reporting group title	Lucentis
Reporting group description:	
Lucentis Intravitreal injection of 0.05 mL (0.5mg)	

Reporting group values	LUBT010	Lucentis	Total
Number of subjects	299	301	600
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	38	89
From 65-84 years	226	238	464
85 years and over	22	25	47
Age continuous Units: years			
arithmetic mean	73.2	73.5	
standard deviation	± 8.75	± 7.9	-
Gender categorical Units: Subjects			
Female	151	146	297
Male	148	155	303

End points

End points reporting groups	
Reporting group title	LUBT010
Reporting group description:	
LUBT010 (proposed ranibizumab biosimilar) Intravitreal injection of 0.05 mL (0.5mg).	
Reporting group title	Lucentis
Reporting group description:	
Lucentis Intravitreal injection of 0.05 mL (0.5mg)	

Primary: Mean change in best corrected visual acuity (BCVA) from baseline in the study eye at the end of 12 months, assessed with the ETDRS chart

End point title	Mean change in best corrected visual acuity (BCVA) from baseline in the study eye at the end of 12 months, assessed with the ETDRS chart
End point description:	
The primary efficacy endpoint of change in BCVA from baseline in the study eye at the end of 12 months was analyzed using analysis of covariance (ANCOVA).	
End point type	Primary
End point timeframe:	
from baseline to 12 months	

End point values	LUBT010	Lucentis		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	295	296		
Units: BCVA letter score (Letters)				
median (full range (min-max))	11 (-36 to 52)	11 (-22 to 45)		

Statistical analyses

Statistical analysis title	ANCOVA model
Statistical analysis description:	
To prove the products to be biosimilar, CI (90% for United States, 95% for the rest of the world) for the difference in mean change in BCVA from baseline in the study eye at the end of 12 months, within prespecified equivalence margin.	
Comparison groups	LUBT010 v Lucentis
Number of subjects included in analysis	591
Analysis specification	Pre-specified
Analysis type	equivalence[1]
P-value	> 0.05 [2]
Method	ANCOVA
Parameter estimate	Least Square Mean
Point estimate	0.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.82
upper limit	1.88
Variability estimate	Standard error of the mean

Notes:

[1] - Equivalence was met.

[2] - There was no statistical significance between LUBT010 and Lucentis.

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
AEs occurring during the study from date of informed consent until end of study visit.	
Adverse event reporting additional description:	
AEs (ocular or non-ocular) were recorded.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Details of safety analysis and split of serious adverse events and non-serious adverse events to be provided.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported